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MAR 15 2007

US Application No.: 10/772,997
Amtd. Dated March 15, 2007
Reply to Office Action of Sept. 18, 2006

AMENDMENTS TO THE DRAWINGS

The attached sheets of drawings (included in the APPENDIX) are new sheets (for this application) corresponding to Figures 1-6, already described in the application. These figures are included in the parent application (Application No. 10/140,512) and incorporated by reference in the present application. As such, the addition of these new sheets adds no new matter.

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REMARKS

Applicants respectfully request reconsideration and withdrawal of the objections and rejections made in the Office Action of September 18, 2006, in view of the foregoing amendments and following remarks.

The Claims and Claim Amendments

Independent claim 1 is hereby amended by addition of the limitation that the treated human or mammal treated in the claimed method (i) is obese prior to initiation of the growth hormone treatment; (ii) has impaired appetite regulation which causes excessive food intake; and (iii) is on an unrestricted diet during the treatment period. The application as originally filed provides support throughout for this amendment (see, e.g., original claim 5, which is cancelled herein; paragraphs 0016-0017, 0010, 0053, and original claim 8; and paragraph 0087, respectively (for sake of convenience reference to portions of the specification herein are made using the paragraph numbering provided in the unmodified and published version of the application - US Patent Publication No. 20050171003)). Applicants amend claim 2 merely to improve the grammar and style of the claim (i.e., this amendment is non-substantive and non-narrowing). New claims 21-27 are directed to additional particular aspects of Applicants' invention which are supported by the originally filed specification (as reflected in, e.g., paragraphs 0036, 0009, 0055, and 0045 of the '003 publication). No new matter is added by these amendments to the claims and no new search is believed to be required based on these amendments. Applicants hereby cancel claims 4, 8-10, 14, 19, and 20, without prejudice or disclaimer, so as to focus prosecution in this application on the aspect of Applicants' invention embodied in the remaining claims. Only claims 1-3, 6, and 21-27 are pending and at issue. Of the pending claims, claim 1 is the only independent claim.

The Specification as Amended is in Proper Form

The Office Action objected to the specification for lack of drawings corresponding to the figures described in this application. Applicants provide herewith new drawing sheets corresponding to these figures (Figs. 1-6), in accordance with the Examiner's suggestion in the Office Action and pursuant to 37 CFR 1.81(c) and 37 CFR 1.121(d). The Office Action notes that the drawings are contained in the parent application (10/140,512), which

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is incorporated by reference in this application, contains these drawings. As such, the addition of these figures adds no new matter.

The Application Sufficiently Enables One of Ordinary Skill to Practice the Claimed Invention

The Office Action rejected all of the previously pending claims (i.e., claims 1-6, 8-11, 14, and 19-20) under 35 USC § 112, first paragraph, as allegedly encompassing subject matter that is beyond what is enabled by the subject patent application. Applicants respectfully submit that this rejection is misplaced and should be withdrawn, particularly in view of the amendments made herein and information submitted herein/herewith.

The Office Action makes the following specific allegations in support of the enablement rejections:

- The conclusions from a literature review of the appetite effect of GH on various species are inconclusive,
- There is not a clear animal model for human testing,
- The specification provides only mixed results of GH on appetite suppression,
- Applicant has only tested GH for suppressing appetite/food intake in obese rats, and
- Applicant has not given a clear indication of what amount constitutes an “appetite suppression effective amount.”

In response to these rejections, and to address these particular issues, Applicants submit herewith the Declaration of Dr. Kjell Malmlöf. In his Declaration, Dr. Malmlöf, one of the named inventors (for this patent application), clearly establishes (1) that the apparent inconclusiveness in the literature is in fact due to a difference in whether the subject/patient to be treated is obese at the time of treatment or not, (2) that the obese female Wistar rat model used in the subject application is an effective predictive model for humans in respect of obesity therapies and also effects of growth hormone, and (3) that the results described in the specification are consistent with the different effects of GH in non-obese and obese mammals. Dr. Malmlöf’s Declaration further sets forth additional corroborating data that evidence the operability of the claimed invention in the model system used in the similar experiments of the patent application.

In respect of the claim element “appetite-suppressing effective amount,” Applicants respectfully submit that the application sufficiently enables one of ordinary skill in the art to

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determine such an amount, which will, predictably, vary with the characteristics of the patient, growth hormone composition administered to the patient, etc. For example, paragraph 0045 of the patent application discusses suitable dosages in practicing the claimed invention (i.e., that can serve as an appetite suppressive amount) and sets forth the factors that a practitioner should consider in setting a particular dose for a particular patient. As is indicated in the application, "A convenient daily dosage of GH is typically in the range of from about 0.001 mg/kg to about 2.0 mg/kg, preferably from about 0.01 mg/kg to about 1.0 mg/kg. The therapeutic dose of the compound will depend upon the frequency and mode of administration, the sex, age, weight and general condition of the subject treated, the nature and severity of the condition treated and any concomitant diseases to be treated and other factors evident to those skilled in the art." Applicants further note that even if the Office should retain its rejection against claim 1 based on the "appetite-suppressing effective amount" element, it should have no such grounds for rejecting new claim 22 or any claims dependent on new claim 22.

In view of these facts and evidence, Applicants respectfully submit that the enablement rejections are misplaced and should be withdrawn.

Conclusion

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Commissioner is hereby authorized to charge any fees in connection with this application and to credit any overpayments to Deposit Account No. 14-1447. The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

Respectfully submitted,

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